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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Dermatologic and Ophthalmic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 18 and 19, 2000, 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Grand Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly L. Topper, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12534. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 18 and 19, 2000, the committee will discuss two new drug applications (NDA's): NDA 18–662, Accutane® (isotretinoin) capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne; and NDA 21–177, (new formulation) isotretinoin capsules, Hoffmann-LaRoche, Inc., for severe recalcitrant nodular acne.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 7, 2000. Oral presentations from the public will be scheduled between approximately oc00165

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1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 7, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: \_ July 11, 2000

Linda A. Suydam, Senior Associate Commissioner.

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CERTIFIED TO BE A TRUE